REMARKS

Claims 1-16 are pending in the instant application. Claims 3-16 have been withdrawn from consideration by the Examiner and subsequently canceled by Applicants in this amendment. Claims 1 and 2 have been rejected. Claims 1 and 2 have been amended. Support for these amendments are provided at page 7, line 33 through page 8, line 1, and page 23, lines 31 through 34 of the instant specification. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed July 31, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled nonelected claims 3-16, without prejudice. In light of the finality of this Restriction Requirement, however, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Amendment of Title

The Examiner suggests that the current title of the invention is not descriptive because the elected claims include

only compositions and has requested that a new title clearly indicative of the invention to which the claims are directed be provided. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the title to the following: LUNG SPECIFIC GENES.

Withdrawal of this objection is therefore respectfully requested.

III. Rejection of Claims 1-2 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 1 and 2 have been rejected under 35 U.S.C. § 101 because the Examiner suggests that the claimed invention lacks patentable utility due to its not being supported by a specific, substantial and credible utility or, in the alternative, a well-established utility. The Examiner suggests that while data are supplied for several sequences, such as SEQ ID NO:1 on pages 97-99, no data therein indicate any specificity regarding the elected SEQ ID NO:12.

Claims 1 and 2 have also been rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most

nearly connected, to make and/or use the claimed sequence. Specifically, the Examiner suggests that since the claimed invention is not supported by a specific, substantial and credible utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Applicants respectfully traverse this rejection.

The usefulness of SEQ ID NO:12 as a lung specific gene is taught throughout the application. See, for example, page 7, line 33, through page 8, line 25; page 9, lines 4-17; and page 32, line 14, through page 33, line 9. In addition, identification of SEQ ID NO: 12 as a microarray candidate for lung cancer and its overexpression in cancerous tissue samples is disclosed at page 94, line 15, through page 96, line 30, of the instant application.

Further, in an earnest effort to advance the prosecution of this case, Applicants are submitting herewith a Declaration by co-inventor Dr. Roberto Macina providing data for SEQ ID NO:12 similar to that provided for SEQ ID NO:1 in the application and confirmative of the specific, substantial and credible utility of SEQ ID NO:12 taught in the instant application. As discussed in paragraph 4 of Dr. Macina's Declaration, experiments confirming the utility of SEQ ID NO:12 with regard to lung cancer were

performed in accordance with the Quantitative Polymerase Chain Reaction (QPCR) protocol taught at page 107-108 of the instant application. The protocol used for these confirmatory experiments is set forth in paragraph 5 of Dr. Macina's Declaration and correlates with the protocol taught in the instant application at pages 107-108. Results from the QPCR experiments demonstrating the sensitivity of SEQ ID NO:12 with regard to lung cancer are summarized in paragraph 6 of Dr. Macina's Declaration and shown in the Figures at pages 5&6 attached to the Declaration. Color copies of these Figures have also been provided at pages 7&8 of the Declaration as the positive results confirming utility of SEQ ID NO:12 are much easier to see in a color format. As shown by these Figures and discussed in paragraph 6 of Dr. Macina's Declaration, the sensitivity calculated comparing levels of SEQ ID NO:12 in lung cancer samples versus the expression in lung normal adjacent tissue from the same patients was 58% while the sensitivity calculated comparing the cancer samples versus the median of eight normal lung samples was 47%. Thus, these data generated and in accordance with experimental protocols taught in the instant application confirm that SEQ ID NO:12 is at least as sensitive as many useful therapeutic and diagnostics currently in

commercial use. See paragraph 7 of Dr. Macina's Declaration.

Withdrawal of these rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

IV. Rejection of Claims 1-2 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1 and 2 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner has acknowledged the specification to meet the written description requirements for SEQ ID NO:12 but suggests that the specification provides insufficient written description to support the genus encompassed by the claims. Specifically, the Examiner suggests that gene sequences, gene sequences that hybridize to the antisense sequence of SEQ ID NO:12, and variants do not meet the written description provision of 35 U.S.C. § 112, first paragraph.

Applicants respectfully traverse this rejection.

In accordance with MPEP 2163, an adequate written

description of the invention may be shown by any description of sufficient, relevant and identifying characteristics so long as a person skilled in the art would recognize that the inventor has possession of the claimed invention. In the instant application, there is an explicit teaching of polynucleotides with the characteristic of 97% identity to SEQ ID NO: 12 and the capability of hybridizing under stringent conditions to an antisense sequence of SEQ ID NO: 12. Specifically, at page 23, lines 31 through 34, it is taught that polynucleotides of 97% identity are a preferred embodiment of polynucleotides which hybridize under stringent conditions. Additional specific information regarding such sequences is not required since identifying polynucleotides sharing 97% identity and hybridizing under stringent conditions with a disclosed sequence are well known in the art and need not be described in detail in the specification. See e.g. MPEP § 2163 and Hybriditech, Inc. v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to polynucleotides having characteristics identified in the written description of the instant application. Specifically, in

accordance with teachings at page 23, lines 31 through 34, claim 1 has been amended to be drawn to a LSG comprising a polynucleotide of SEQ ID NO:12, a polypeptide expressed by a polynucleotide of SEQ ID NO:12, or a polynucleotide with 97% identity to SEQ ID NO: 12 and which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 12. Further, without conceding correctness of the Examiner's position, applicants have also amended claim 1 to delete language relating to variant sequences.

The claims as amended clearly meet the written description requirements of 35 U.S.C. § 112, first paragraph. Withdrawal of this rejection is therefore respectfully requested.

V. Rejection of Claims 1-2 under 35 U.S.C. § 112, second paragraph

Claims 1 and 2 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Thus, in earnest effort to advance the prosecution of this case but without conceding correctness of the Examiner's position, Applicants have amended the claims in accordance with the Examiner's suggestion to claim

only those embodiments which are part of the elected invention; to define the abbreviation LSG and to remove the phrase "or variant thereof". Further, Applicants have amended claim 1 to state that the polynucleotide has 97% identity with SEQ ID NO:12 thereby pointing out the stringent conditions that are intended to allow the polynucleotide to hybridize. Support for these amendments can be found at page 7, line 33 through page 8, line 1, where LSG is defined, and page 23, lines 31-34 wherein stringent conditions are defined.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is respectfully requested in light of these amendments.

VI. Rejection of Claims 1 and 2 under 35 U.S.C. § 102(b)

Claim 1 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Sigma (1990). The Examiner suggests that the Sigma Catalog teaches an oligomer O 3003 that matches a segment of SEQ ID NO:12 (nucleotide positions 575-578). The Examiner suggests that the language "a polynucleotide of" in claim 1 is supportive of the concept that subsequences such as short oligomers are included.

Applicants respectfully traverse this rejection.

MPEP § 2111.03 is quite clear; the meaning of transitional

phrases other than "comprising", "consisting essentially of" and "consisting of" must be interpreted in light of the teachings of the specification. Teachings of the specification, particularly at pages 19-25 make clear that by the phrase "of" SEQ ID NO:12, Applicants in no way mean to encompass an oligomer such as O 3003 that matches only a 3 nucleotide base segment of SEQ ID NO:12. Accordingly, the Examiner's suggestion that the Sigma Catalog teaching an oligomer O 3003 that matches nucleotide positions 575-578 of SEQ ID NO:12 anticipates the instant claimed invention is improper.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

Claims 1 and 2 have also been rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Bandman et al. (2001). The Examiner suggests that Bandman et al. discloses a sequence (SEQ ID NO:16) which contains an identical matching polynucleotide sequence (nucleotide positions 79-705, col. 75-78) to a fragment of SEQ ID NO:12 of the instant claims. The Examiner suggests that Bandman et al. also teaches a protein encoded by SEQ ID NO:16 and a polynucleotide sequence which hybridizes under stringent conditions to the polynucleotide encoding the polypeptide of SEQ ID NO:4. Accordingly, the

Examiner suggests that Bandman et al. teaches all the limitations of claims 1 and 2.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that Bandman et al. is not a valid reference under 35 U.S.C. § 102(b) with respect to the instant application since the priority date of the instant application, July 21, 2000 is prior to the March 20, 2001 issue date of the Bandman et al. patent.

Further, as discussed in detail in Section IV *supra*, claims of the instant application have been amended to clarify that a LSG comprises a polynucleotide of SEQ ID NO:12, a polypeptide expressed by a polynucleotide of SEQ ID NO:12, or a polynucleotide with 97% identity to SEQ ID NO: 12 and which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 12.

In contrast, Bandman et al. teaches a sequence similar merely to nucleotide positions 79-705 of SEQ ID NO:12. Accordingly, since this reference does not teach a polynucleotide of SEQ ID NO:12, a polypeptide encoded by a polynucleotide of SEQ ID NO:12 nor a polynucleotide with 97% identity to SEQ ID NO: 12, it cannot anticipate the claims as amended.

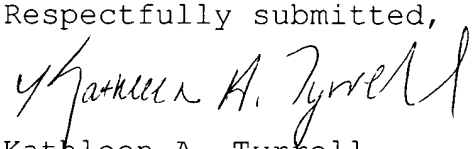
Withdrawal of this rejection under 35 U.S.C. § 102(b) is

therefore respectfully requested.

VIII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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